IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

ROZLYN ACKERMANN, Individually and as Personal Representative of the Estate of MARTIN LINDSEY ACKERMANN, Deceased, Plaintiff,	)	
vs.	)	CIVIL ACTION NO. 4-05-cv-0084-MHS-DDB
WYETH PHARMACEUTICALS, Defendant.	)	

AMENDED REPLY MEMORANDUM IN SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY JUDGMENT (STATE LAW)

SUBMITTED PURSUANT TO LEAVE GRANTED IN THE COURT'S AUGUST 21, 2006 ORDER

TABLE OF CONTENTS

I. The Learned Intermediary Doctrine Bars Plaintiff's Claims. ..... - 2 -

A. Dr. Sonn Was Both Warned And Aware Of Alleged Suicide-Related Risks. ..... - 2 -

B. Plaintiff Cannot Establish That Inadequate Warnings Were A "But For" Cause. ..... - 4 -

II. Texas Civil Practice & Remedies Code § 82.007(a) Bars Plaintiff's Claims. ..... - 7 -

A. Plaintiff Has Not Rebutted TCPRC § 82.007(a)'s Conclusive Presumption. ..... - 7 -

B. TCPRC § 82.007(b)(1) Is Preempted ..... - 8 -

C. TCPRC § 82.007(b)(1) Should Be Severed. ..... - 10 -

D. Plaintiff's "No Warnings" Distinction Fails. 10

E. Plaintiff's Constitutional Challenge Fails. 11

III. Plaintiff's Warranty Claims Fail. ..... - 14 -

IV. Plaintiff's Texas Deceptive Trade Practice Act Claim Fails. ..... - 15 -

V. Plaintiff's Fraud And Misrepresentation Claims Fail. ..... - 15 -

Exhibit 1 8/11/06 Declaration of Thomas M. Sonn, M.D.

Pursuant to the Court's August 21, 2006 Order granting defendant Wyeth leave to submit an amended reply memorandum of up to 15 pages, Wyeth submits this amended reply:

I. The Learned Intermediary Doctrine Bars Plaintiff's Claims.

Plaintiff admits that, if it applies, the learned intermediary doctrine bars her claims. (Pl's Am. Resp. at 1-2). She asserts, however, that the treating physician, Dr. Thomas Sonn, was not warned or aware of Effexor's suicide-related risks. (*Id.* at 3-6). She also asserts that there are disputed facts regarding causation because (a) Dr. Sonn was not asked the right question in his deposition; (b) she may test his credibility at trial; (c) a "black box" warning would have altered the treatment; (d) a "heeding presumption" satisfies her burden; and (e) a "reasonably objective" physician test overcomes Dr. Sonn's testimony.[1] (*Id.* at 4-11). These arguments fail.

A. Dr. Sonn Was Both Warned And Aware Of Alleged Suicide-Related Risks.

Plaintiff asserts that Wyeth "'does not argue in its motion for summary judgment that the warnings to Dr. [Sonn] regarding [Effexor] were legally adequate.'" (Pl's Am. Resp. at 2 (citation omitted)). But Wyeth made – and substantiated – precisely that argument. (Mem. Supp. at 9-11). Multiple decisions applying the learned intermediary doctrine under Texas law have found that, as a matter of law, warnings like Effexor's were adequate.[2] (*See* Mem. Supp. at 9).

Separately, Wyeth showed that Dr. Sonn was aware of the relevant risks, which is an independent basis for applying the learned intermediary doctrine even if the warnings were inadequate. (Mem. Supp. at 11-14). Dr. Sonn always considered suicide when treating

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[1] Plaintiff also asserts that overpromotion overcomes the learned intermediary doctrine. (Pl's Am. Resp. at 12). But she cites no Texas authority to that effect. And, in any event, it does not apply here because there is no evidence of overpromotion. (*See* Sonn Dep. at 196:7-9 (Ex. C to Mem. Supp.) ("Q. Back in 2001 or 2002, do you have any specific recollection of a Wyeth rep calling on you? A. Not – not that far back.")); *see also* Pl's Am. Resp. at 26-27 ("Dr. Sonn remembers absolutely nothing … sales representatives told him")).

[2] Wyeth's opening memorandum (at 9, 10) cited *McNeil v. Wyeth*, No. 3-02-CV-2072-L, 2005 U.S. Dist. LEXIS 3477 (N.D. Tex. Mar. 4, 2005). The Fifth Circuit recently reversed. *McNeil v. Wyeth*, No. 05-10509, 2006 U.S. App. LEXIS 21499 (5th Cir. Aug. 22, 2006).

depressed patients; was aware of and considered claims that Effexor "could have some causative effect related to suicide or suicidality;" and knew that some patients taking Effexor attempt suicide. (*Id.* at 12-14). Dr. Sonn believes today that he was "adequately warned" about Effexor's risks when he treated Ackermann. (*Id.* at 11).

According to plaintiff, however, Dr. Sonn needed to know that (a) "in a 'small, vulnerable sub-population' of patients, Effexor can trigger suicide;" and (b) "Wyeth concedes that Effexor can trigger suicidality for some patients." (Pl's Am. Resp. at 4-5, 6). Relying primarily on *Garside v. Osco Drug, Inc.*, 976 F.2d 77 (1st Cir. 1992), she asserts that only "unequivocal" knowledge identical to her proposed warning will suffice.[3] (Pl's Am. Resp. at 3-4). She is incorrect. *Garside* rejected the treater's affidavit because it did not say he was aware of the risk at the time of treatment, and the additional language from *Garson* plaintiff quotes is *dictum*. 976 F.2d at 82.

More fundamentally, whatever Dr. Sonn knew, *he treated Martin Ackermann as if there were a real suicide risk.* In *Eck v. Parke, Davis & Co.*, 256 F.3d 1013 (10th Cir. 2001), the Tenth Circuit applied the learned intermediary doctrine under Oklahoma law on similar facts. The treating doctor there was "aware of a 'scientific hypothesis'" that a drug interaction might exist, but not "certain of the interaction." *Id.* at 1022. The physician had substantially the same knowledge as the plaintiff's proposed warning because she considered the risk in her treatment. *Id.* Indeed, the *Eck* plaintiffs quoted the same *dictum* from *Garside* that plaintiff here relies on,

[3] Plaintiff also quotes the court's observation in *In re Norplant Contraceptive Prods. Liab. Litig.*, 955 F. Supp. 700, 710 (E.D. Tex. 1997) (Schell, J.), *aff'd*, 165 F.3d 374 (5th Cir. 1999), that the physicians there "'testified **unequivocally**.'" (Pl's Am. Resp. at 4 (*quoting Norplant,* 955 F. Supp. at 710) (plaintiff's emphasis)). But plaintiff deletes the end of the sentence, which shows their "unequivocal" testimony was not, as plaintiff suggests, about knowledge of health effects. It was "that none of the information shown to them ... would have changed their minds about whether to prescribe Norplant." 955 F. Supp. at 710-11. Dr. Sonn was as "unequivocal" on that point.

and the Tenth Circuit found it unpersuasive. *Id.* at 1022-23.[4] Dr. Sonn was warned and aware of a suicide risk in January 2002, so the learned intermediary doctrine bars plaintiff's claims.

B. Plaintiff Cannot Establish That Inadequate Warnings Were A "But For" Cause.

Wyeth established that the additional warnings plaintiff claims were required would not have changed Dr. Sonn's treatment decisions. Plaintiff thus cannot meet her learned intermediary burden to show that a warnings failure was a "but for" cause of Ackermann's suicide. (Mem. Supp. at 14-15). Plaintiff's response is that, because Dr. Sonn wasn't asked the right question at his deposition, we simply don't know. (Pl's Am. Resp. at 4-5). Plaintiff is wrong. Dr. Sonn testified that, with the information plaintiff claims was required, he still would prescribe Effexor and warn today as he did in 2002. (*See* Sonn Dep. at 157:3-13, 127:16-19, 130:5-8 (Ex. C. to Mem. Supp.)). Moreover, Wyeth has now asked Dr. Sonn the question plaintiff says should have been asked. As stated in his attached declaration, had Dr. Sonn been given plaintiff's warning, nothing would have changed. (8/11/06 Sonn Decl. at ¶¶ 3, 4 (Ex. 1 hereto)).[5]

Plaintiff's four other arguments fail. First, she argues that, although Dr. Sonn's testimony relates to an issue solely within his knowledge, she may test his credibility at trial because his cooperation with Wyeth's counsel shows bias. (Pl's Am. Resp. at 7-9). But Dr. Sonn provided plaintiff's counsel a statement and also was willing to meet with them. (Sonn. Dep. at 193:23-195:16 (Ex. B to Pl's Am. Resp.)). Moreover, "merely recit[ing] the incantation,

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[4] *Accord Miller v. Pfizer, Inc.*, 196 F. Supp. 2d 1095, 1129 n.106 (D. Kan. 2002) (rejecting claim that *Garside* required finding that treating physician's knowledge was inadequate), *aff'd on other grounds*, 356 F.3d 1326 (10th Cir.), *cert. denied*, 543 U.S. 917 (2004).

[5] Declarations submitted with a summary judgment reply may be considered where, as here, there is an opportunity to respond. *See Travelers Ins. Co. v. Liljeberg Enters., Inc.*, 7 F.3d 1203, 1207 (5th Cir. 1993).

'Credibility,' and hav[ing] a trial on the hope that a jury may disbelieve factually uncontested proof" is not enough.[6] *Curl v. IBM*, 517 F.2d 212, 214 (5th Cir. 1975) (citation omitted).

Plaintiff also asserts that, because Dr. Sonn said he relays "black box" warnings to patients, he would have communicated with the Ackermanns differently had there been a "black box" warning. (Pl's Am. Resp. at 8). But Dr. Sonn would convey a suicide-related "black box" warning only because he thought FDA regulations require that. (Sonn Dep. at 125:25-126:9 (Ex. B to Pl's Am. Resp.)). In fact, they do not. *See United States v. Evers*, 643 F.2d 1043, 1048 (5th Cir. 1981) (FDA does not regulate the practice of medicine). Moreover, "black box" warnings cannot be given without prior FDA approval.[7] What Dr. Sonn might have done with a "black box" warning that Wyeth could not give is irrelevant.

Next, plaintiff asserts that a "heeding presumption" satisfies her burden to show causation. She cites *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1281 (5th Cir. 1974), to suggest that Texas recognizes that presumption. (Pl's Am. Resp. at 10-11). *Reyes*, however, did not involve a learned intermediary. *See id.* at 1277. Plaintiff also identifies only one Texas federal trial court applying a "heeding presumption" to learned intermediaries, although many courts, including higher ones, have not. *E.g.*, *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir.

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[6] Courts have rejected similar claims by this plaintiff's counsel before. In *Woulfe v. Eli Lilly Co.*, 965 F. Supp. 1478 (E.D. Okla. 1997), Mr. Vickery alleged that the physician was "in [a pharmaceutical manufacturer's] pocket" because he executed an affidavit for the defense. "Plaintiff seems to be making the argument that any affidavit or testimony submitted by a witness in support of a party's defense is inherently suspect and subject to a finding that the witness is controlled by that party. The court will not countenance such implausible reasoning." *Id.* at 1486. In *Miller*, Mr. Vickery alleged that the physician was biased because he consulted with the pharmaceutical manufacturer. 196 F. Supp. 2d at 1129 n.108. The *Miller* court said that this "attack on [the treater's] credibility d[id] not create a genuine issue of material fact" and entered summary judgment. *Id.*; *see also Eck*, 256 F.3d at 1023-24 (physician's receipt of research funding from defendant did not create fact issue).

[7] "Black box" warnings "are permitted ... only when specifically required by the FDA." Labeling and Prescription Drug Advertising; Content and Format for Labeling for Human Prescription Drugs, 44 Fed. Reg. 37,434, at 37,448 (June 26, 1979); *see Ehlis v. Shire Richwood, Inc.*, 233 F. Supp. 2d 1189, 1198 (D.N.D. 2002) (claim that "black box" warning should have been added found preempted), *aff'd on other grounds*, 367 F.3d 1013 (8th Cir. 2004).

1999); *see generally Koenig v. Purdue Pharma Co.*, No. 3:04-CV-01590, 2006 U.S. Dist. LEXIS 38412, at *13-17 (N.D. Tex. May 23, 2006) (collecting authorities).

Moreover, if a "heeding presumption" applied, "'heed' in this context means only that the learned intermediary would have incorporated the 'additional' risk into his decisional calculus." *Thomas v. Hoffmann-LaRoche, Inc.*, 949 F.2d 806, 814 (5th Cir. 1992) (Mississippi law) (footnotes omitted), *cert. denied*, 504 U.S. 956 (1992). It is wrong to "construe [the treating physician] 'heeding' an adequate warning to mean [he] would have *given* the warning." *Eck*, 256 F.3d at 1021 (emphasis in original). Further, a "heeding presumption" is rebutted where, as here, the physician says different warnings would not have made a difference. *E.g., id.*; *Stafford v. Wyeth*, 411 F. Supp. 2d 1318, 1321 (W.D. Okla. 2006) (Oklahoma law).

Finally, plaintiff argues that a fact issue exists based on what a "reasonably objective" physician would have done if warned. (Pl's Am. Resp. at 11). But she relies on decisions applying Mississippi law.[8] Texas learned intermediary decisions routinely look to what the treating physician – not what a "reasonably objective" physician—would have done. *E.g.*, *Porterfield*, 183 F.3d at 468; *Brumley v. Pfizer, Inc.*, 149 F. Supp. 2d 305, 313 (S.D. Tex. 2001); *accord Stafford*, 411 F. Supp. 2d at 1322 (Oklahoma law); *Woulfe*, 965 F. Supp. at 1484 (same). Plaintiff cannot show "that a proper warning would have changed the decision of the intermediary to prescribe the product." *Brumley*, 149 F. Supp. 2d at 313. The learned intermediary doctrine thus bars her claims.

[8] Plaintiff relies on *Thomas* and *Hermes v. Pfizer, Inc.*, 848 F.2d 66 (5th Cir. 1988). (Pl's Am. Resp. at 11). Both applied Mississippi law. *Thomas* said the issue is whether "an adequate warning would have convinced the *treating physician* not to prescribe the product." 949 F.2d at 812 (emphasis added). While *Thomas* said that might be established with "objective evidence of how a reasonable physician would have responded," *Thomas* did not consider whether that could overcome the treating physician's own testimony. *Id.* In *Hermes*, the prescribing physician was a plaintiff's expert, and the opinion does not set forth his testimony on the causation issue.

II. Texas Civil Practice & Remedies Code § 82.007(a) Bars Plaintiff's Claims.

To attempt to overcome Texas Civil Practice and Remedies Code ("TCPRC") § 82.007(a)'s conclusive presumption, plaintiff makes five arguments. Specifically, she asserts that (1) she rebutted the presumption under TCPRC § 82.007(b)(1) by showing that Wyeth withheld information from the FDA; (2) TCPRC § 82.007(b)(1) is not preempted; (3) even if TCPRC § 82.007(b)(1) were preempted, the Court should ignore the statute's severability clause and strike the entire statute; (4) TCPRC § 82.007 does not apply because there purportedly was no warning; and (5) TCPRC § 82.007 is unconstitutional. Each argument fails.

A. Plaintiff Has Not Rebutted TCPRC § 82.007(a)'s Conclusive Presumption.

Plaintiff attempts to invoke TCPRC § 82.007(b)(1), which rebuts TCPRC § 82.007(a)'s presumption if a plaintiff shows that a "defendant ... withheld from ... the [FDA] required information that was material and relevant to the performance of the product and was causally related to the claimant's injury." (Pl's Am. Resp. at [20]). Her entire showing is that: "because Wyeth deems suicidality as being 'labeled,' it does not report either foreign suicides or suicide attempts, by patients taking Effexor, to the FDA." (Pl's Am. Resp. at 20). But TCPRC § 82.007(b)(1) applies only when the withheld information was "*required* information." TCPRC § 82.007(b)(1) (emphasis added). The FDA does not routinely require companies to report "foreign suicides or suicide attempts."

"Adverse drug experiences" may be subject to either 15-day or periodic reporting requirements. 21 C.F.R. § 314.80(c)(1), (2). They must be reported in 15 days if they are "both serious *and unexpected*." *Id.* at § 314.80(c)(1) (emphasis added). An "[u]nexpected adverse drug experience" is one "not listed in the current labeling." *Id.* at § 314.80(a). Because suicides and suicide attempts long have been reported to the FDA and reflected in Effexor's FDA-approved labeling, they are neither "unexpected" nor subject to the 15-day reporting requirement.

Adverse drug experiences not subject to the 15-day reporting requirement generally must be provided to the FDA annually. *Id.* at § 314.80(c)(2). But "foreign marketing experience" is *excluded* from the annual reporting requirement. *Id.* at § 314.80(c)(2)(iii). Plaintiff has not shown that Wyeth withheld "required information" from the FDA, so Wyeth is "not liable" for alleged "failure[s] to provide adequate warnings." TCPRC § 82.007(a).

B. TCPRC § 82.007(b)(1) Is Preempted.

Even if plaintiff had made a showing that satisfied TCPRC § 82.007(b)(1), that section is preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). (*See* Mem. Supp. at 17-21). Although courts considering similar provisions have found them preempted under *Buckman*, plaintiff asserts that *Buckman* applies only to state-law causes of action that require a showing of "reliance by the FDA." (Pl's Am. Resp. at 13-15). According to plaintiff, *Buckman* does not apply here because TCPRC § 82.007(b)(1) is not such a cause of action. (*Id.*). Plaintiff is incorrect.

In finding a state-law, fraud-on-the-FDA cause of action preempted, *Buckman* reasoned that those claims would interfere with the FDA's exclusive authority to enforce the FDCA. "[C]omplying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants – burdens not contemplated by Congress in enacting the FDCA." *Id.* at 350. "[A]pplicants [would] fear that their disclosures to the FDA, although deemed appropriate by the Agency, will later be judged insufficient in state court" and, thus, "have an incentive to submit a deluge of information that the [FDA] neither wants nor needs, resulting in additional burdens on the FDA[]." *Id.* at 351. "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for [FDCA] noncompliance" by expressly barring private rights of action. *Id.* at 349 n.4 (*citing* 21 U.S.C. § 337(a)).

Although TCPRC § 82.007(b)(1) is not a cause of action, it implicates *Buckman*'s concerns about interfering with the FDA every bit as directly. Plaintiff's TCPRC § 82.007(b)(1) showing seeks to subject Wyeth to tort liability – to remove a conclusive presumption of non-liability – based on a claim that, although there has been no such finding by the FDA, Wyeth's FDA submissions were materially incomplete. As in *Buckman*, if plaintiff is permitted to proceed under TCPRC § 82.007(b)(1), manufacturers will "fear that their disclosures to the FDA, although deemed appropriate by the Agency, will later be judged insufficient in state court." 531 U.S. at 351. They will also "have an incentive to submit a deluge of information that the [FDA] neither wants nor needs, resulting in additional burdens on the FDA[]." *Id.* The fact that TCPRC § 82.007(b)(1) is not itself a cause of action makes no difference at all for these purposes.

Similarly, plaintiff asserts that, unlike TCPRC § 82.007(b)(1), the Michigan statute at issue in *Garcia* and *Henderson* "contain[ed] the critical element of reliance by the FDA" in that it required a showing that, but for the nondisclosure, the FDA would have withdrawn approval for the drug. (Pl's Am. Resp. at 14-15). This argument fails because it incorrectly assumes that only causes of action requiring a showing of "reliance by the FDA" are preempted under *Buckman*.[9] In *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir.), *cert. denied*, 126 S. Ct. 420 (2005), the Sixth Circuit found a state-law negligence *per se* claim based on FDCA violations preempted under *Buckman*. Because neither a negligence *per se* claim nor TCPRC § 82.007(b)(1) has an express FDA reliance requirement, *Cupek* establishes that, under *Buckman*, TCPRC § 82.007(b)(1) is preempted.

[9] TCPRC 82.007(b)(1)'s materiality and relevance requirements also implicate the FDA's decision-making process just as a reliance requirement does.

C. TCPRC § 82.007(b)(1) Should Be Severed.

Plaintiff argues that, if TCPRC § 82.007(b)(1) is preempted, the entire statute falls with it because any other result would give Wyeth a "'get out of jail free' card." (Pl's Am. Resp. at 18-20). This argument does not pass "Go." The bill that contained TCPRC § 82.007 had a severability provision: if any provision is "held invalid, the invalidity does not affect other provisions or applications" of the statute "that can be given effect without the invalid provision or application." 2003 Tex. Gen. Laws 204, § 23.03. Section 82.007(a) "can be given effect" even though § 82.007(b)(1) is preempted on these facts, particularly since (a) TCPRC § 82.007(b)(1) is preempted only in part (*i.e.*, it is preempted only when, as here, the FDA has not found it was defrauded); and (b) with a proper factual basis, plaintiff could have attempted to satisfy any of the other rebuttal provisions in TCPRC § 82.007(b)(2)-(5). The severability language controls and, as the *Garcia*, *Henderson*, and *Kobar* courts found when addressing similar statutes (*see* Mem. Supp. at 21), the rest of the statute can and should be given effect.[10]

Tellingly, plaintiff's response quotes "'[t]he test for severability in the *absence of* an express severability clause.'" (Pl's Am. Resp. at 20 (*quoting Association of Tex. Prof'l Educ. v. Kirby*, 788 S.W.2d 827, 830-31 (Tex. 1990)) (emphasis added)). That test, although satisfied here, does not apply because the bill containing TCPRC § 82.007 had a severability clause.

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[10] The Sixth Circuit's analysis in *Garcia* is instructive:

> We find that Plaintiff has failed to persuade us that the district court erred as a matter of law, and that given a choice between immunity absent a finding of bribery or fraud by the Federal Government and no immunity, the Michigan Legislature would prefer the former option. First, it appears that the Michigan Legislature was concerned that unlimited liability for drug manufacturers would threaten the financial viability of many enterprises and could add substantially to the cost and unavailability of many drugs. Second, and most importantly, severing the preemption exemptions will not give license to drug manufacturers to use bribery or fraud as a means of obtaining FDA approval, then rely on that approval as a shield from products liability: it will merely place responsibility for prosecuting bribery or fraud on the FDA in the hands of the Federal Government rather than the state courts.

Garcia v. Wyeth-Ayerst Labs., 385 F.3d 961, 967 (6th Cir. 2004) (citation omitted).

TCPRC § 82.007(a)'s conclusive presumption applies even though, on these facts, federal law preempts TCPRC § 82.007(b)(1).

D. Plaintiff's "No Warnings" Distinction Fails.

Plaintiff asserts that this is a "no warnings" case and, therefore, TCPRC § 82.007 does not apply. (Pl's Am. Resp. at 20-22). She relies on TCPRC § 82.007(a)'s initial clause, which says the statute applies "'[i]n a products liability action alleging that an injury was caused by a failure to provide **adequate** warnings or information with regard to a pharmaceutical product.'" (Pl's Am. Resp. at 21 (*quoting* TCPRC § 82.007(a)) (plaintiff's emphasis)). According to plaintiff, this somehow means that "the statutory presumption should apply if, and only if, a particular risk has been disclosed to the FDA [by the defendant] and is actually included in the FDA approved package insert." (*Id.*). Plaintiff is wrong for three reasons.

First, her interpretation bears no relationship to the statute's language. The clause plaintiff relies on says nothing about whether "a particular risk [must] ha[ve] been disclosed to the FDA" or whether the risk must have been "actually included in the FDA approved package insert." *See* TCPRC § 82.007(a). Plaintiff apparently divines those requirements, as well as a rule excluding cases in which no warnings were provided, from the statute's use of the word "adequate." This is wishful thinking. The statute says it applies whenever a plaintiff alleges "a failure to provide adequate warnings" *or* "a failure to provide adequate … information." *See id.* Both easily encompass instances in which no warnings were given, and neither says anything about what was disclosed to the FDA or what was included in the FDA-approved package insert.

Second, and even if plaintiff's interpretation of the statute were correct, this is not a "no warnings" case; there *was* a warning. In plaintiff's words, "[t]here was a … precaution about **depression**-induced suicidality," and she thinks that warning should also have mentioned a risk of drug-induced suicide. (*Id.* (emphasis in original)). Indeed, plaintiff's characterization of this

as a "no warnings" case illustrates why her interpretation of the statute is incorrect. Every failure-to-warn plaintiff asserts, as plaintiff asserts here, that there were "no warnings" in the sense that, whatever warnings were provided, different or additional ones purportedly were required. If that were enough to render the statute inapplicable, the statute would be meaningless.

Third, even if the statute applied "if, and only if, a particular risk has been disclosed to the FDA [by the defendant] and is actually included in the FDA approved package insert" (*id.*), it would apply here. As explained in Wyeth's preemption-based summary judgment motion, the FDA was aware of and assessed possible suicide-related risks of Effexor and other modern antidepressants for more than a decade before Ackermann's January 2002 suicide, and its assessment was that the then-existing suicide-related warnings struck the appropriate balance. (*See* Mem. Supp. Mot. Partial Summ. Judgment [Federal Preemption] at 5-13).

E. Plaintiff's Constitutional Challenge Fails.

Plaintiff's final attack on TCPRC § 82.007 is that it violates the Texas Constitution's "Open Courts" provision (art. I, § 13).[11] (Pl's Am. Resp. at 22-25). As plaintiff concedes (Pl's Am. Resp. at 23), a statute is unconstitutional under the "Open Courts" provision only if "the litigant [has] a cognizable common law cause of action that is being restricted." *Rose v. Doctors Hosp.*, 801 S.W.2d 841, 843 (Tex. 1990) (citation omitted); *accord Lucas v. United States*, 757 S.W.2d 687, 690 (Tex. 1988). Plaintiff's claims here, however, are wrongful death and survival claims. They are not "common law cause[s] of action" because they survived or were created by

[11] The "Open Courts" provision provides: "All courts shall be open, and every person for an injury done him, in his lands, goods, person or reputation, shall have remedy by due course of law." Tex. Const. art I, § 13. Federal Rule of Civil Procedure 24(c) requires (a) "the court [to] notify the attorney general of the State as provided in" 28 U.S.C. § 2403(b) when, as here, a party challenges the constitutionality of a state statute; and (b) the "party challenging the constitutionality of legislation [to] ... call the attention of the court to" this obligation. Because plaintiff failed to advise the Court of this obligation, defendant now provides the Court with notice.

Martin Ackermann's death only by virtue of the Texas wrongful death and survival statutes. Thus, they are not subject to the "Open Courts" provision.

As the Texas Supreme Court observed in *Rose*, "[l]ike all actions based upon theories of negligence, the [plaintiffs'] cause of action was a common law claim. It would have died with [the plaintiffs' decedent] had it not been preserved by the legislature in the wrongful death statute. The [plaintiffs'] remedy, therefore, was conferred by statute, not by the common law. Because the [plaintiffs] do not seek a common law remedy, the open courts provision does not apply to their wrongful death claim." 801 S.W.2d at 845 (citation omitted). Similarly, in *Horizon/CMS Healthcare Corp. v. Auld*, 34 S.W.3d 887, 902-04 (Tex. 2000), the Court found that, "[b]ecause ... survival actions would not exist absent legislative enactment, they are derived not from the common law but from a statute." (Citation omitted).

Plaintiff relies on *Lucas* (Pl's Am. Resp. at 22), a case that, unlike this one, involved neither wrongful death nor survival claims. She ignores *Auld* and relegates *Rose* to a footnote, purporting to distinguish it because the statute at issue there supposedly was expressly limited to wrongful death actions. (Pl's Am. Resp. at 23 n.25). In plaintiff's view, while TCPRC § 82.007 "would likely survive a constitutional challenge on this basis" if it were "drafted to apply only to wrongful death claims," it is not and, thus, "is unconstitutional on its face." (Pl's Am. Resp. at 23. n.25). Plaintiff is flat wrong. The statute at issue in *Rose* – Tex. Rev. Civ. Stat. Ann. art. 4590i, § 11.02 (repealed 2003) – was *not* expressly limited to wrongful death actions.[12] And

[12] Tex. Rev. Civ. Stat. Ann. art. 4590i, § 11.02, which was repealed in 2003, provided that:

> Limit on Civil Liability
>
> (a) In an action on a health care liability claim where final judgment is rendered against a physician or health care provider, the limit of civil liability for damages of the physician or health care provider shall be limited to an amount not to exceed $500,000.

Rose analyzed at length why, due to the statute's severability clause, it was constitutional and applied to wrongful death claims even though, as applied to common law claims, it was unconstitutional. 801 S.W.2d at 844-45. Indeed, *Auld, Rose*, and *Lucas* all considered the constitutionality of the same statute. *See Auld*, 34 S.W.3d at 901-04, *Rose*, 801 S.W.2d at 845-46, *Lucas*, 757 S.W.2d at 689-92. The fact that plaintiff's claims are not common law causes of action defeats her constitutional challenge to TCPRC § 82.007.

Separately, a party challenging a statute's constitutionality under the "Open Courts" provision must also show that "the restriction [created by the statute] is unreasonable or arbitrary when balanced against the purpose and basis of the statute." *Rose*, 801 S.W.2d at 843 (citation omitted); *accord Lucas*, 757 S.W.2d at 690. Plaintiff attempts to make this showing by attacking the Texas legislature for its supposed "overwhelming political one sidedness" and arguing that TCPRC § 82.007 reflects the legislature going too "far ... in drafting laws to further their respective political positions." (Pl's Am. Resp. at 24). Inflamed rhetoric, however, is not enough. As explained in Wyeth's preemption-based summary judgment motion, it is neither "unreasonable [n]or arbitrary" to limit a prescription drug manufacturer's liability for failing to provide warnings that the FDA considered, rejected, and believes would have violated federal law had they been provided. (*See* Mem. Supp. Mot. Partial Summ. Judgment [Federal Preemption] at 5-13).

III. Plaintiff's Warranty Claims Fail.

Plaintiff abandons her express warranty claim by failing to identify any express warranty that Wyeth extended or allegedly breached. (*See* Mem. Supp. at 24-25). To avoid the lack of an

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(continued...)

> (b) Subsection (a) of this section does not apply to the amount of damages awarded on a health care liability claim for the expenses of necessary medical, hospital, and custodial care received before judgment or required in the future for treatment of injury.

Effexor sale here, she invokes pre-strict liability authorities dispensing with privity for consumer good warranty claims. (Pl's Am. Resp. at 25-26). But the issue here is not a lack of *privity*; it is the lack of a *sale* by Wyeth. Warranty claims "require[] an underlying 'sale'" and fail if "there is no sale" by the defendant. *Sanchez v. Liggett & Myers, Inc.*, 187 F.3d 486, 491 (5th Cir. 1999).

Plaintiff also submits an affidavit stating that the "medical care" Martin Ackermann purchased from Dr. Sonn supposedly included the Effexor. (R. Ackermann Aff. (Ex. J to Pl's Am. Resp.)). But *Wyeth* never sold Martin Ackermann's Effexor sample pack to anyone. (*See* Mem. Supp. at 23-24, 28). No matter what plaintiff says she bought from *Dr. Sonn*, *Wyeth* was not a "seller." *See* Tex. Bus. & Comm. Code § 2.103(1), (4), § 2.106(a); *see also* Mem. Supp. at 23-24 (discussing authorities). Plaintiff's warranty claims fail.

IV. Plaintiff's Texas Deceptive Trade Practice Act Claim Fails.

Plaintiff does not dispute that, since the alleged Texas Deceptive Trade Practice Act ("DTPA") violations are purported breaches of warranty, her DTPA claim fails with her warranty claims. She argues that, even though Ackermann did not purchase or seek to purchase Effexor, he was a DTPA "consumer" because the medical services he bought from Dr. Sonn supposedly included Effexor. (Pl's Am. Resp. at 25-26 & Ex. K). But, just as purchases from *Dr. Sonn* do not create a warranty claim against *Wyeth*, they do not create a DTPA claim. (*See* Mem. Supp. at 26-28). Finally, plaintiff asserts it would be "premature" to determine now whether a DTPA claim survives death. (Pl's Am. Resp. at 25 n.25). But summary judgment is not a premature time to rule, and the better view is that DTPA claims do not survive. (Mem. Supp. at 28-29).

V. Plaintiff's Fraud And Misrepresentation Claims Fail.

Plaintiff concedes she cannot establish reliance, so her fraud and misrepresentation claims fail. (Pl's Am. Resp. at 26-27). Those claims, too, should be dismissed.

Dated: August 28, 2006

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document has been filed electronically on the 28th day of August 2006, and is available for viewing and downloading from the Eastern District of Texas ECF system. Notice of Electronic Case Filing has been sent automatically to all parties listed below and in the ECT Case service List in effect on the date of electronic filing, which constitutes service of same, and satisfies the requirements of Fed. R. Civ. P. 5(b)(2)(D)

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